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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/403,654 10/25/99 AMMERMANN

E 47968

EXAMINER

HM12/0717

KEIL & WEINKAUF
1101 CONNECTICUT AVENUE NW
WASHINGTON DC 20036

KRUSE, D

ART UNIT

PAPER NUMBER

1638

DATE MAILED:

07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/403,654

Applicant(s)

AMMERMANN ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-36,39 and 41-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-36,39 and 41-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>g</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 37, 38, 40, 47 and 48 have been canceled, Claims 49-51 have been added as requested in the response filed 10 May 2001.
2. The Information Disclosure Statement filed 10 May 2001 is acceptable.
3. The Title remains objected to, the Examiner suggests the following title:
Expression of a BAS 490F Fungicide-Binding Antibody Fragment In Plants That Confers Tolerance.
4. The figures remain objected to by the Draftsman.
5. The Specification remains objected to because it lacks a Brief Description of the Drawings, which should occur after the Summary of the Invention.
6. The objection to Claim 42 is withdrawn in view of Applicant's amendment.
7. The rejection of Claims 39 and 45 under 35 U.S.C. § 101 is withdrawn in view of Applicant's amendments.
8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

9. Claims 29-36, 39 and 41-46 remain rejected and 49-51 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last

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Office action mailed 7 December 2000. Applicant's arguments filed 10 May 2001 have been fully considered but they are not persuasive.

Applicant does not specifically argue the rejection. Applicant only states on page 5 of the response that disclosure of the scFv encoding nucleotide sequence itself is of minor importance to the underlying novel and inventive method.

The Examiner maintains the rejection, because of the nature of the invention, disclosure of at least one nucleotide sequence encoding an scFv that binds BAS 490F, that would confer upon a plant transformed with said nucleotide sequence tolerance to BAS 490F is required.

10. Claims 29-36, 39 and 41-46 remain rejected and 49-51 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 7 December 2000. Applicant's arguments filed 10 May 2001 have been fully considered but they are not persuasive.

Applicant only argues the points of the rejection of claims 29-36, 39 and 41-46 under 35 U.S.C. § 112 first paragraph for enablement in view of expression of a gene encoding a BAS 490F-binding antibody or binding fragment thereof in a transformed plant (pages 2-5 of the response). Applicant argues that the instant invention provides a novel way for producing herbicide-resistant or -tolerant plants by expressing an "exogenous" polypeptide, antibody or part of an antibody, and that only the availability of

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the herbicide as a chemical compound itself is sufficient to produce a herbicide--tolerant or resistant transgenic plant (pages 2 and 3 of the response). In addition, Applicant argues that the method for producing the specific antibody against an exogenous antigen and the steps how to clone the relevant gene coding for said antibody is disclosed in the specification (page 3 of the response, last paragraph). Applicant argues that the scFv encoding nucleotide sequence itself and its disclosure is of minor important to the underlying novel and inventive method (response, page 5).

The Examiner responds, disclosure of the scFv encoding nucleotide sequence itself is not of minor importance. The likelihood of one of skill in the art reisolating the specific scFv encoding nucleotide sequence of the instant invention is very remote. The transformed plant at Claim 46 requires extensive guidance, and does require at least one disclosed nucleotide sequence to be disclosed in order for one of skill in the art to produce. Applicant has only provided general guidance for the isolation of genes encoding antibody-related polypeptides. Examiner reiterates that Applicant has not provided guidance for isolation of the genus of nucleotide sequences which encode peptides that bind BAS 490F, e.g. the fungicide's target cytochrome c oxidoreductase, mutations thereof or fragments thereof, or binding peptides that do not fall in to the category of antibody (page 7 of the 7 December 2000 Office action). It would have required undue trial and error experimentation for one of skill in the art at the time of Applicant's invention to identify and isolate genes encoding all peptides that bind BAS 490F in addition to transforming plants with said isolated genes and identifying those genes that would produce BAS 490F tolerance in the transformed plants.

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10. Claim 29-36, 42-44, 46 and 49-51 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claims 29-32, the term "exogenous" remains unclear, the Examiner suggests the term -- heterologous -- which is widely understood in the art. The term "exogenous" insinuates a peptide outside of the transformed plant.

Claims 30 and 31 are indefinite because the phrase "A process" should read -- The process -- in reference to claim 29. In addition, at Claim 31 line 3, the phrase "a fragment" should read -- a binding fragment --.

At Claim 32, the phrases "a signal peptide" and "an ER retention signal" are indefinite because the claimed expression cassette is composed of nucleic acids and not amino acids.

At Claims 32 and 35, the phrase "(or a part thereof)" should not be in parentheses.

Claims 33-36 are indefinite because the phrase "An expression cassette" should read -- The expression cassette -- in reference to claim 32.

Claims 42-44 are indefinite because the phrase "A process" should read -- The process -- in reference to claim 41. The phrase "with the aid of" is indefinite and should read -- by --. In addition, the claims should further limit the "introducing" step and not "transformation".

At Claim 46 line 2, the term "tolerance" is relative, the claim should state that the claimed plant has "increased tolerance" relative to a wild type or non-transformed plant.

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Claim 49 is indefinite because the phrase "A process" should read -- The process -- in reference to the claim 41. In addition, at line 3 the term "comprises" should read -- encodes -- because the expression cassette comprises nucleic acids not amino acids.

Claim 50 is indefinite because the phrase "A process" should read -- The process -- in reference to the claim 42.

Claim 51 is indefinite because the phrase "An expression cassette" should read -
- The expression cassette -- in reference to claim 33.

Conclusion

11. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Paula Hutzell can be reached at (703) 308-4310. The fax telephone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3419.



AMY J. NELSON, PH.D.
PRIMARY EXAMINER

David H. Kruse, Ph.D.
13 July 2001